

Amendments to the Claims:

The following listing of claims will replace all prior versions, and listings, of claims in the application:

1-20. (Canceled)

21. (Currently Amended) A therapeutic device intended for substantially fully intracorporeal insertion for treatment of an obstruction in the prostatic portion of a male urethra, comprising:

a non-biodegradable element that is designed to be placed and retained in a prostatic portion of the male urethra to maintain a channel, said element being sufficiently flexible to conform to the urethra, but sufficiently rigid to maintain the channel for urine flow in the prostatic portion, the channel providing for passage of urine from upstream of the obstruction to downstream of the obstruction; and

a cytoreductive agent that causes reduction of the obstruction, said cytoreductive agent being positioned along said element, so as to treat the obstruction of the prostatic portion of the male urethra; when said element is retained in the prostatic portion of the male urethra,

wherein the reductive effect is through direct contact of said element with cells of the obstruction and even without removing the device from the urethra, the reductive effect ceases when the direct contact ceases, and

wherein said device further comprises a withdrawal thread and is non-traumatically removable from the male urethra by said withdrawal thread following treatment of the obstruction.

22. (Previously Presented) The device of claim 21, wherein said device is configured to be self-stabilizing.

23. (Previously Presented) The device of claim 21, wherein said element is of cylindrical shape.

24. (Previously Presented) The device of claim 21, wherein said cytoreductive agent is selectively reductive to cells of the obstruction.

25. (Previously Presented) The device of claim 21, wherein said cytoreductive agent is cytotoxic to prostatic cells.

26. (Previously Presented) The device of claim 21, wherein said cytoreductive agent is reductive to urethral mucosal cells.

27. (Previously Presented) The device of claim 21, wherein said cytoreductive agent extends around a perimeter of said element.

28. (Previously Presented) The device of claim 21, wherein said cytoreductive agent is supported by said element.

29. (Previously Presented) The device of claim 21, wherein said cytoreductive agent is distinct from said element and covers said element.

30. (Previously Presented) The device of claim 21, wherein said cytoreductive agent is located on or in a sleeve, which is positioned along said non-biodegradable element.

31. (Previously Presented) The device of claim 21, wherein said cytoreductive agent is incorporated in said element.

32. (Previously Presented) The device of claim 21, wherein said element comprises (i) a core made of a biocompatible material and (ii) a biologically active zone, and wherein in the biologically active zone of said element, said biocompatible material of said core incorporates said cytoreductive agent, at least on a surface of said biologically active zone.

33. (Previously Presented) The device of claim 32, wherein said core made of biocompatible material is made of silicone rubber.

34. (Previously Presented) The device of claim 21, wherein said element comprises an internal core made of a biocompatible material, and said cyto-reductive agent is located on or in a biologically compatible substrate covering at least a portion of said internal core.

35. (Previously Presented) The device of claim 34, wherein said internal core is made of silicone rubber.

36. (Previously Presented) The device of claim 34, wherein said substrate and said internal core are off-centered in relation to one another.

37. (Previously Presented) The device of claim 34, wherein said element has an outer surface, wherein said substrate is radially expandable, and wherein said substrate has an outer surface that is inscribed within said outer surface of said element, and, in the expanded position, emerges from said outer surface of said element.

38. (Previously Presented) The device of claim 34, wherein said substrate is hydrophilic and expandable under the effect of biological fluids present or circulating in the obstructed prostatic portion of the male urethra.

39. (Previously Presented) The device of claim 34, further comprising a sheath made of a synthetic foam between said substrate and said internal core.

40. (Previously Presented) The device of claim 34, wherein said substrate comprises a plurality of radial channels.

41. (Previously Presented) The device of claim 21, wherein said device comprises a bacteriostatic agent.

42. (Previously Presented) The device of claim 21, comprising means for checking the correct positioning of said device.

43. (Previously Presented) The device of claim 21, comprising an agent which is opaque vis-a-vis X-rays.

44. (Previously Presented) The device of claim 21, wherein said cytoreductive agent is not hydrosoluble.

45. (Previously Presented) The device of claim 21, wherein said cytoreductive agent comprises at least one medicament selected from the group consisting of antimitotic agents, cytolytic agents, enzymes, hormones, antienzymes, and metal salts.

46. (Previously Presented) The device of claim 21, wherein said element comprises a bottom end and a top end, and wherein said cytoreductive agent is positioned between said bottom end and said top end of said element.

47. (Currently Amended) ~~The device of claim 46,~~ A therapeutic device intended for substantially fully intracorporeal insertion for treatment of an obstruction in the prostatic portion of a male urethra, comprising:

_____ a non-biodegradable element that is designed to be placed and retained in a prostatic portion of the male urethra to maintain a channel, said element being sufficiently flexible to conform to the urethra, but sufficiently rigid to maintain the channel for urine flow in the prostatic portion, the channel providing for passage of urine from upstream of the obstruction to downstream of the obstruction; and

_____ a cytoreductive agent that causes reduction of the obstruction, said cytoreductive agent being positioned along said element, so as to treat the obstruction of the prostatic portion of the male urethra when said element is retained in the prostatic portion of the male urethra,

_____ wherein said element comprises a bottom end and a top end, and wherein said cytoreductive agent is positioned between said bottom end and said top end of said element,

_____ wherein said top end of said element is blind, and includes at least one perforation in order to ensure the passage of urine, and

_____ wherein said device further comprises a withdrawal thread and is non-traumatically removable from the male urethra by said withdrawal thread following treatment of the obstruction.

48. (Previously Presented) The device of claim 21, wherein said cytoreductive agent is cytotoxic to urethral mucosal cells.

49. (Previously Presented) A method of treating an obstruction of the prostatic portion of the male urethra, comprising inserting said device of claim 21 into the obstructed portion of the male urethra, thereby opening the obstructed urethra and allowing normal passage of urine from the bladder.

50. (Previously Presented) The method of claim 49, wherein said cytoreductive agent causes a reduction in the obstruction.

51-52. (Canceled)

53. (Previously Presented) The method of claim 50, further comprising removing said device once sufficient reduction has occurred that normal urine flow can be achieved in the absence of said device.

54. (Previously Presented) The method of claim 49, wherein the obstruction is a tumoral obstruction.

55. (Previously Presented) The method of claim 54, wherein said cytoreductive agent erodes the tumoral obstruction.

56. (Previously Presented) The method of claim 49, further comprising temporarily maintaining said device in the male urethra and then removing said device from the male urethra.

57. (Currently Amended) A therapeutic device intended for substantially fully intracorporeal insertion for treatment of an obstruction in a natural lumen through which a fluid naturally flows, comprising:

a non-biodegradable element that is designed to be placed and retained in the natural lumen to maintain a channel, said element being sufficiently flexible to conform to the natural lumen, but sufficiently rigid to maintain the channel for flow of the fluid in the lumen, the channel providing for passage of the fluid from upstream of the obstruction to downstream of the obstruction with respect to natural fluid flow; and

a cytoreductive agent that causes reduction of the obstruction, said cytoreductive agent being positioned along said element, so as to treat the obstruction of the natural lumen when said element is retained in the natural lumen,

wherein the reductive effect is through direct contact of said element with cells of the obstruction and, even without removing the device from the lumen, the reductive effect ceases when the direct contact ceases, and

wherein said device further comprises a withdrawal thread and is non-traumatically removable from the natural lumen by said withdrawal thread following treatment of the obstruction.

58. (Previously Presented) The device of claim 57, wherein said device is configured to be self-stabilizing.

59. (Previously Presented) The device of claim 57, wherein said element is of cylindrical shape.

60. (Previously Presented) The device of claim 57, wherein said cytoreductive agent is selectively reductive to cells of the obstruction.

61. (Previously Presented) The device of claim 57, wherein said cytoreductive agent is cytotoxic to cells of a wall of said lumen.

62. (Previously Presented) The device of claim 57, wherein said cytoreductive agent is reductive to urethral mucosal cells.

63. (Previously Presented) The device of claim 57, wherein said cytoreductive agent extends around a perimeter of said element.

64. (Previously Presented) The device of claim 57, wherein said cytoreductive agent is supported by said element.

65. (Previously Presented) The device of claim 57, wherein said cytoreductive agent is distinct from said element and covers at least a portion of said element.

66. (Previously Presented) The device of claim 57, wherein said cytoreductive agent is located on or in a sleeve, which is positioned along said non-biodegradable element.

§, 67. (Previously Presented) The device of claim 57, wherein said cytoreductive agent is incorporated in said element.

68. (Previously Presented) The device of claim 57, wherein said element comprises (i) a core made of a biocompatible material, and (ii) a biologically active zone, and wherein in the biologically active zone of said element, said biocompatible material of the core incorporates said cytoreductive agent.

69. (Previously Presented) The device of claim 68, wherein said core made of biocompatible material is made of silicone rubber.

70. (Previously Presented) The device of claim 57, wherein said element comprises an internal core made of a biocompatible material, and said cytoreductive agent is located on or in a biologically compatible substrate covering at least a portion of said internal core.

71. (Previously Presented) The device of claim 70, wherein said internal core is made of silicone rubber.

72. (Previously Presented) The device of claim 70, wherein said cytoreductive agent and said internal core are off-centered in relation to one another.

73. (Previously Presented) The device of claim 70,
wherein said element has an outer surface,
wherein said substrate is radially expandable, and
wherein said substrate has an outer surface that is inscribed within said outer surface of said element, and, in the expanded position, emerges from said outer surface of said first element.

§ 74. (Previously Presented) The device of claim 70, wherein said substrate is hydrophilic and expandable under the effect of biological fluids present or circulating in the obstructed natural lumen.

75. (Previously Presented) The device of claim 70, comprising a sheath made of a synthetic foam between said cytoreductive agent and said internal core.

76. (Previously Presented) The device of claim 70, wherein said substrate comprises a plurality of radial channels.

77. (Previously Presented) The device of claim 57, wherein said device comprises a bacteriostatic agent.

78. (Previously Presented) The device of claim 57, comprising means for checking the correct positioning of said device.

79. (Previously Presented) The device of claim 57, comprising an agent which is opaque vis-a-vis X-rays.

80. (Previously Presented) The device of claim 57, wherein said cytoreductive agent is not hydrosoluble.

81. (Previously Presented) The device of claim 57, wherein said cytoreductive agent comprises at least one medicament selected from the group consisting of antimitotic agents, cytolytic agents, enzymes, hormones, antienzymes, and metal salts.

82. (Previously Presented) The device of claim 57, wherein said element comprises a bottom end and a top end and wherein said cytoreductive agent is positioned between said bottom end and said top end of said element.

83. (Previously Presented) The device of claim 82, wherein said cytoreductive agent is positioned between 10 and 15 mm from both said bottom end and said top end of said element.

84. (Currently Amended) ~~The device of claim 82,~~ A therapeutic device intended for substantially fully intracorporeal insertion for treatment of an obstruction in a natural lumen through which a fluid naturally flows, comprising:
a non-biodegradable element that is designed to be placed and retained in the natural lumen to maintain a channel, said element being sufficiently flexible to conform to the natural lumen, but sufficiently rigid to maintain the channel for flow of the fluid in the lumen, the channel providing for passage of the fluid from upstream of the obstruction to downstream of the obstruction with respect to natural fluid flow; and
a cytoreductive agent that causes reduction of the obstruction, said cytoreductive agent being positioned along said element, so as to treat the obstruction of the natural lumen when said element is retained in the natural lumen,
wherein said element comprises a bottom end and a top end, and wherein said cytoreductive agent is positioned between said bottom end and said top end of said element,
wherein said top end of said element is blind, and includes at least one perforation in order to ensure the passage of the fluid, and

wherein said device further comprises a withdrawal thread and is non-traumatically removable from the natural lumen by said withdrawal thread following treatment of the obstruction.

85. (Currently Amended) ~~The device of claim 57, further comprising A~~
therapeutic device intended for substantially fully intracorporeal insertion for treatment of an obstruction in a natural lumen through which a fluid naturally flows, comprising:

a non-biodegradable element that is designed to be placed and retained in the natural lumen to maintain a channel, said element being sufficiently flexible to conform to the natural lumen, but sufficiently rigid to maintain the channel for flow of the fluid in the lumen, the channel providing for passage of the fluid from upstream of the obstruction to downstream of the obstruction with respect to natural fluid flow;

a cytoreductive agent that causes reduction of the obstruction, said cytoreductive agent being positioned along said element, so as to treat the obstruction of the natural lumen when said element is retained in the natural lumen; and

an other element attached to said non-biodegradable element by a flexible connection,

wherein said device further comprises a withdrawal thread and is non-traumatically removable from the natural lumen by said withdrawal thread following treatment of the obstruction.

86. (Previously Presented) The device of claim 85, wherein said other element does not comprise or support a cytoreductive agent.

87. (Previously Presented) The device of claim 85, wherein said other element comprises a core made of a biocompatible but non-biodegradable material.

88. (Previously Presented) The device of claim 87, wherein said biocompatible but non-biodegradable material of said other element is silicone rubber.

89. (Previously Presented) The device of claim 85, wherein at least a portion of said other element is radially expandable.

90. (Currently Amended) A method of treating an obstruction of a natural lumen, comprising inserting said device of claim ~~57~~85 into the obstructed natural lumen so that said element is positioned in contact with the obstruction, thereby opening the obstructed natural lumen and allowing normal passage of the fluid.

91. (Previously Presented) The method of claim 90, wherein said cytoreductive agent causes a reduction in the obstruction.

92. (Previously Presented) The method of claim 91, wherein said cytoreductive agent causes the reduction in the obstruction when in direct contact with the obstruction.

93. (Previously Presented) The method of claim 92, wherein said cytoreductive agent gradually ceases to cause the reduction in the obstruction as direct contact of said device with the obstruction ceases.

94. (Previously Presented) The method of claim 91, further comprising removing said device once sufficient reduction has occurred that the natural lumen can function normally in the absence of said device.

95. (Previously Presented) The method of claim 91, wherein the obstruction is a tumoral obstruction.

96. (Previously Presented) The method of claim 95, wherein said cytoreductive agent erodes the tumoral obstruction.

97. (Previously Presented) The method of claim 90, further comprising temporarily maintaining said device in the natural lumen and then removing said device from the natural lumen.

98. (Currently Amended) A therapeutic device intended for substantially fully intracorporeal insertion for reduction of a pre-existing obstruction in a natural lumen for flow

of a fluid, the lumen being obstructed by the effect of a local cell proliferation, said device comprising:

a non-biodegradable element adapted to be placed and retained in the natural lumen to maintain a channel, and sufficiently flexible to conform to the natural lumen, but sufficiently rigid to maintain the channel for flow of the fluid in the natural lumen, the channel providing for passage of the fluid from upstream to downstream of the obstruction with respect to the natural fluid flow; and

a sleeve which is supported by said element and which is positioned along said element so as to come into contact with the obstruction when said element is retained in the natural lumen, wherein said sleeve supports or comprises a cytoreductive agent that causes reduction of the pre-existing obstruction,

wherein the reductive effect is through direct contact of said sleeve with cells of the obstruction and, even without removing the device from the lumen, the reductive effect ceases when the direct contact ceases.

99. (Previously Presented) The device of claim 98, wherein said cytoreductive agent is selectively reductive to cells of the obstruction.

100. (Previously Presented) The device of claim 98, wherein said device is an intraurethral therapeutic device and wherein the fluid is urine, which is allowed to pass from upstream to downstream of the obstruction.

101. (Previously Presented) A method of treating a pre-existing obstruction of a natural lumen, comprising inserting said device of claim 98 into the obstructed natural lumen so that said element is positioned in contact with the obstruction, thereby opening the obstructed natural lumen and allowing normal passage of the fluid.

102. (Previously Presented) A method for treating a pre-existing obstruction in the prostatic portion of a male urethra, comprising inserting said device of claim 100 into the

obstructed portion of the male urethra, thereby opening the obstructed urethra and allowing normal passage of urine.

103. (Previously Presented) The method of claim 101, wherein the obstruction is a tumoral obstruction.

104. (Previously Presented) The method of claim 103, wherein said agent erodes the obstruction.

105. (Currently Amended) A therapeutic device intended for substantially fully intracorporeal insertion for treatment of an obstruction in a natural lumen through which a fluid naturally flows, comprising:

a non-biodegradable element that is designed to be placed and retained in the natural lumen to maintain a channel, said element being sufficiently flexible to conform to the natural lumen, but sufficiently rigid to maintain the channel for flow of the fluid in the lumen, the channel providing for passage of the fluid from upstream of the obstruction to downstream of the obstruction with respect to natural fluid flow; and

a cytoreductive agent that causes reduction of the obstruction, said cytoreductive agent being positioned along said element, so as to treat the obstruction of the natural lumen when said element is retained in the natural lumen,
_____ wherein said cytoreductive agent is non-selectively cytotoxic, and
_____ wherein the reductive effect is through direct contact of said element with cells
of the obstruction and, even without removing the device from the lumen, the reductive effect ceases when the direct contact ceases.

106. (Previously Presented) The device of claim 105, wherein said natural lumen is the prostatic portion of a male urethra.

107. (Previously Presented) A method of treating an obstruction of a natural lumen, comprising inserting said device of claim 105 into the obstructed natural lumen so that

said element is positioned in contact with the obstruction, thereby opening the obstructed natural lumen and allowing the normal passage of the fluid.

108. (Previously Presented) A method for treating an obstruction in the prostatic portion of a male urethra, comprising inserting said device of claim 106 into the obstructed portion of the male urethra, thereby opening the obstructed urethra and allowing normal passage of urine.

109. (Currently Amended) A therapeutic device intended for substantially fully intracorporeal insertion for treatment of an obstruction in a natural lumen through which a fluid naturally flows, comprising:

a non-biodegradable element that is designed to be placed and retained in the natural lumen to maintain a channel, said element being sufficiently flexible to conform to the natural lumen, but sufficiently rigid to maintain the channel for flow of the fluid in the lumen, the channel providing for passage of the fluid from upstream of the obstruction to downstream of the obstruction with respect to natural fluid flow; and

a cytoreductive agent that causes reduction of the obstruction, said cytoreductive agent being positioned along said element, so as to treat the obstruction of the natural lumen when said element is retained in the natural lumen,

wherein said reductive effect is through direct contact of said ~~device~~ element with cells of the obstruction and, even without removing the device from said lumen, the reductive effect ceasing ceases when the direct contact ceases.

110. (Previously Presented) The device of claim 109, wherein said natural lumen is the prostatic portion of a male urethra.

111. (Previously Presented) A method of treating an obstruction of a natural lumen, comprising inserting said device of claim 109 into the obstructed natural lumen so that

said element is positioned in contact with the obstruction, thereby opening the obstructed natural lumen and allowing the normal passage of the fluid.

112. (Previously Presented) A method for treating an obstruction in the prostatic portion of a male urethra, comprising inserting said device of claim 110 into the obstructed portion of the male urethra, thereby opening the obstructed urethra and allowing normal passage of urine.

113-120. (Canceled)

121. (Previously Presented) A therapeutic device intended for substantially fully intracorporeal insertion for treatment of an obstruction in a natural lumen through which a fluid naturally flows, comprising:

§, a non-biodegradable element that is designed to be placed and retained in the natural lumen to maintain a channel, said element being sufficiently flexible to conform to the natural lumen, but sufficiently rigid to maintain the channel for flow of the fluid in the lumen, the channel providing for passage of the fluid from upstream of the obstruction to downstream of the obstruction with respect to natural fluid flow; and

a cytoreductive agent that causes reduction of the obstruction, said cytoreductive agent being positioned along a length of said element, so as to treat the obstruction of the natural lumen when said element is retained in the natural lumen;

wherein said cytoreductive agent has a continuous surface both around said element and along said length of said element.

122. (Previously Presented) The device of claim 121, wherein said natural lumen is the prostatic portion of the male urethra.

123. (Previously Presented) A method of treating an obstruction of a natural lumen, comprising inserting said device of claim 121 into the obstructed natural lumen so that

said element is positioned in contact with the obstruction, thereby opening the obstructed natural lumen and allowing the normal passage of the fluid.

124. (Previously Presented) A method for treating an obstruction in the prostatic portion of a male urethra, comprising inserting said device of claim 122 into the obstructed portion of the male urethra, thereby opening the obstructed urethra and allowing normal passage of urine.

125. (Currently Amended) A therapeutic device intended for being substantially fully located in a natural lumen through which a fluid naturally flows, said fluid flow being controlled by a sphincter through said lumen, said device comprising:

§, | a non-biodegradable ~~active~~-tubular element that is designed to be placed in at least an obstructed part of said natural lumen, upstream of said sphincter, said element having a substantially continuous wall and external surface and being sufficiently flexible to conform to said lumen, but sufficiently rigid to maintain a channel for flow of the fluid in the lumen, said channel providing for passage of the fluid flow from upstream of the obstruction to downstream of the obstruction with respect to said natural fluid flow;

| said ~~active~~-element being retained in the downstream direction by said sphincter, and in the upstream direction by ~~passive~~-retaining means linked to said element and to be placed in said lumen downstream of said sphincter;

| said ~~active~~-element comprising a therapeutic agent that causes reduction of the obstruction supported by and arranged around and along said ~~active~~-element to be delivered by contact between said external surface and said obstruction; and

said device being arranged to be inserted into and removed from said lumen in a substantially non-traumatic manner.

126. (Previously Presented) A device as claimed in claim 125, wherein the lumen is a male urethra and the obstructed part is the prostatic portion of said urethra.

127. (Previously Presented) A device according to claim 125, wherein the therapeutic agent is a cytoreductive agent.

128. (Previously Presented) A device according to claim 125, comprising a withdrawal thread at its downstream end, arranged for the non-traumatic removal of said device.

129. (New) A device according to claim 125, wherein said retaining means is not therapeutically active.

130. (New) The device according to claim 125, wherein said natural lumen is the prostatic portion of a male urethra.

131. (New) A method of treating an obstruction of a natural lumen, comprising inserting said device of claim 125 into the obstructed natural lumen so that said element is positioned in contact with the obstruction, thereby opening the obstructed natural lumen and allowing the normal passage of the fluid.

132. (New) A method for treating an obstruction in the prostatic portion of a male urethra, comprising inserting said device of claim 130 into the obstructed portion of the male urethra, thereby opening the obstructed urethra and allowing normal passage of urine.

133. (New) A method of treating an obstruction of a natural lumen, comprising inserting said device of claim 57 into the obstructed natural lumen so that said element is positioned in contact with the obstruction, thereby opening the obstructed natural lumen and allowing the normal passage of the fluid.

134. (New) The device of claim 85, wherein said natural lumen is the prostatic portion of a male urethra.

135. (New) A method for treating an obstruction in the prostatic portion of a male urethra, comprising inserting said device of claim 134 into the obstructed portion of the male urethra, thereby opening the obstructed urethra and allowing normal passage of urine.